

8EHQ-080215181/ MR 61038

RECEIVED  
OPPT CBIC

PUBLIC COPY

2002 AUG -9 AM 5:09

August 7, 2002

Via Federal Express

Document Processing Center (Mail Code 7407M)  
Room 6428  
Attention: 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency, ICC Building  
1201 Constitution Ave., NW  
Washington, DC 20460

COMPANY SANITIZED

Dear 8(e) Coordinator:

Substituted Anthranilamide

This letter is to inform you of the results of a recently completed 4-week study in dogs with the above referenced test material.

The test material was administered to male and female dogs (2 dogs/sex/dose, approximately 6 months old at study start) via capsule at doses of 0, 300 or 1000 mg/kg/day for 4 weeks. Body weights, food consumption, and clinical signs were evaluated weekly. Clinical pathology endpoints were evaluated pretest and on week 4. After 4 weeks of treatment, all dogs were sacrificed and given a gross and microscopic pathological examination.

Hypospermatogenesis was observed in testes of some of the dogs. This change was present in 0 of 2 control male dogs, 1 of 2 male dogs dosed with 300 mg/kg/day, and 2 of 2 male dogs dosed with 1000 mg/kg/day. Due to the small group size and the variability of testicular morphology in young dogs, the relationship of this change to treatment could not be determined. No other findings were observed in the various parameters evaluated. A definitive 4-week study is planned using larger group size to separate background changes from test compound-related changes.

Under these experimental conditions, the finding described above, appears to be reportable, based upon the guidance given in the EPA TSCA Section 8(e) Reporting Guide (1991).

Sincerely,

8EHP-02-15131

880200001675

2002 AUG 29 AM 10:08

RECEIVED  
OPPT NCIC

PUBLIC COPY

CBI Substantiation

Support for [ ] claim of confidential business information for the information claimed as CBI is provided.

1. Confidential treatment should be afforded for ten years. Information should remain confidential until that time [ ]
2. No.
3. [ ] identity and the chemical identity [ ] are only disclosed to a second party [ ] under a nondisclosure (secrecy) agreement. [ ] has not otherwise disclosed the information claimed as CBI to other parties.
4. All documents relating to [ ] are stored in locked, limited-access facilities and designated as proprietary, trade secret or confidential. [ ] having access to the information are contractually prohibited from disclosing [ ] proprietary/confidential information outside the [ ].
5. No.
6. Yes. [ ] Disclosure of the CBI information would permit a competitor to specifically know and understand [ ] efforts and to forego the necessary time and expense to identify/develop this compound, thus capitalizing on [ ]. [ ] believes that a competitor's knowledge of the chemical identity [ ] interest in this compound would give a competitor several years advantage [ ] and would allow it to forego much of the R&D costs that it would otherwise have to bear. [ ].
7. a. No.  
b. Yes. The chemical identity [ ] would, potentially, disclose proprietary mixture [ ].  
c. Yes. Disclosure of [ ] would reveal the identity and source of the [ ].